REMARKS

The amendments to the claims have been made to place the claims in proper form for U.S. examination.

The Examiner is encouraged to telephone the undersigned attorney to discuss any matter that would expedite allowance of the present application.

Respectfully submitted,

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MARKED-UP VERSION OF CLAIM AMENDMENTS

1. A process of analyzing a specimen of biological material in a biochemical or immunological ~~test~~ assay for an analyte, said process comprising the steps of:

providing a specimen of biological material to be analyzed;

depositing said specimen on a substrate;

subjecting ~~the~~ said specimen on said substrate to a treatment ~~which~~ that develops a color ~~correlating~~ correlated to the amount of an analyte in the specimen;

measuring at least one defined ~~color~~ characteristic of said color, said characteristic being selected from the group consisting of hue angle, chroma, saturation and lightness of the developed color; and

analyzing the measurement of said at least one color characteristic to determine the presence or concentration of said analyte in ~~the~~ said specimen.

2. ~~A process according~~ The process of to claim 1, wherein said specimen of biological material comprises liquid ~~and~~ or semi-solid body secretions collected from a patient to be diagnosed for evidence of abnormalities~~,~~;

said analyte to be assayed consists essentially of cancer indicating markers in ~~the~~ said specimen~~,~~; and

the measurement of said at least one color characteristic is used to classify the specimen as normal or abnormal according to the value of the color characteristic so obtained.

3. The process of claim 2, wherein the ~~sample~~ specimen is lung mucus, throat mucus, cervical mucus or seminal fluid.

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4. The process of claim 2 ~~or claim 3~~, wherein said specimen ~~the sample collected from a human patient~~ is deposited on a generally white substrate, and wherein said ~~the~~ process ~~included~~ further comprises developing color from said sample by enzyme reaction~~,~~ ~~determining at least one defined color characteristic selected from a hue angle, chroma or saturation, and lightness of the color so developed, and classifying the sample as normal or abnormal according to the defined characteristic of the color so developed~~.

5. The process ~~according to~~ of claim 1, wherein said specimen of biological material comprises a colon-contacting semi-solid ~~samples~~ sample collected from a patient to be diagnosed for evidence of abnormalities;

said analyte to be assayed consists essentially of carbohydrate markers indicative of abnormalities~~,~~;

~~the~~said step of subjecting ~~the~~ said specimen to a treatment comprises depositing the specimen on a generally white substrate, staining the ~~sample~~ specimen on the substrate with galactose oxidase and color developing the stained ~~sample~~ specimen with ~~Shifts~~ Schiff's reagent~~,~~; and

the measurement of said at least one color characteristic is used to classify the specimen as normal or abnormal according to the value of the color characteristic so obtained.

6. The process of ~~analyzing a specimen of biological material according to~~ claim 1, wherein said specimen of biological material comprises a colon-contacting semi-solid sample collected from a patient to be diagnosed for evidence of abnormalities~~,~~;

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said analyte to be assayed consists essentially of markers indicative of the presence of abnormalities~~,~~;

~~the~~ said step of subjecting ~~the~~ said specimen to a treatment comprises depositing the specimen on a generally white substrate and developing color from the specimen by enzyme reaction; and

the measurement of said at least one ~~defined~~ color characteristic is used to classify the ~~sample~~ specimen as normal or abnormal according to the ~~defined characteristic~~ value of the color ~~so developed~~ characteristic so obtained.

7. The process of ~~any previous claim~~ claim 1, wherein said defined color characteristic to be measured is ~~the~~ hue angle~~,~~ and ~~the~~said hue angle is determined spectrophotometrically.

8. The process of ~~any one of claims 2 to 6~~ claim 1, wherein ~~the~~ said substrate is non-cellulosic.

9. The process of ~~any one of claims 2 to 6~~ claim 1, wherein ~~the~~ said substrate is glass fibre.

10. The process of ~~any one of claims 2 to 6~~ claim 1, wherein ~~the~~ said substrate is substantially pure white.

11. The process ~~on any one of claims 5 to 10~~ of claim 5, wherein ~~the sample~~ said specimen is predominantly a rectal mucus sample.

12. A system ~~of~~ for analysis of liquid or semi-solid body secretion samples obtained from a human ~~patients~~ patient to diagnose for the presence or absence of abnormalities in ~~the~~ said patient~~,~~ by ~~utilization of~~ determination of a defined color

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TRANSLATION

characteristic developed in the sample, ~~and~~ said color characteristic being selected from the group consisting of hue angle, chroma ~~or~~, saturation~~,~~ and lightness, said system comprising:

a white, non-cellulosic substrate with porous ~~"pebbled"~~ pebbled surface, for receiving and holding the sample during development;

a source of galactose oxidase, adapted to apply galactose oxidase to the substrate surface for selective enzymatic oxidation of the sample thereon;

a source of Schiff's ~~Reagent~~ reagent, adapted to apply ~~Schiff's Reagent~~ said reagent to ~~the~~ said oxidized sample on ~~the~~ said substrate for development of an analyzable color therein~~.~~; and

~~and~~ means for presenting the color-developed sample to a portable reflectance spectrophotometer, said spectrophotometer being capable of determining and reporting a defined color characteristic of said samples on said substrate, said color characteristic being selected from the group consisting of hue angle, chroma, ~~or~~ saturation~~,~~ and lightness ~~from stained samples on said substrate~~.

13. A kit for analysis a of colon-contacting semi-solid ~~samples~~ sample obtained from a human ~~patients~~ patient to diagnose for the presence or absence of rectal abnormalities in the patient, said kit comprising;

a generally white, non-cellulosic substrate for receiving ~~the~~ said sample;

a source of Schiff's ~~Reagent~~ reagent; and

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a portable reflectance spectrophotometer said spectrophotometer being capable of determining and reporting at least one defined color characteristic of said sample on said substrate, said color characteristic selected from the group consisting of hue angle, chroma, ~~or~~ saturation~~,~~ and lightness~~, from stained samples on said substrate~~.

14. The kit of claim 13, ~~A kit according to claim 8~~ wherein the substrate is glass fibre.

15. The process of ~~A process according to~~ claim 1, wherein said specimen of biological material is ~~the~~ a skin surface sample from ~~of~~ a patient and said analyte is ~~skin~~ cholesterol.

16. A process ~~of~~ for determining skin cholesterol levels ~~of~~ in a patient, said process comprising the steps of:

applying to the ~~patient's~~ skin surface of said patient a reagent ~~which~~ that selectively binds to skin cholesterol;

causing a color developing chemical reaction with the skin cholesterol-boundary reagent so formed, to form a color complex; and

subjecting the color complex so formed to spectrophotometic analysis to read therefrom a predefined characteristic of ~~the~~ said colored complex, said color characteristic being selected from the group consisting of hue angle, chroma, saturation and lightness.

17. The process of ~~A process according to~~ claim 16, wherein

said reagent ~~which~~ that selectively binds to skin cholesterol is selected from the group consisting of:

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(i) steroid glycosides, containing as an aglycone a cyclopentaneperhydrophenanthrene fragment for the furostanole or spirostanole series, and an ologosaccaride fragment including 3 to 10 monosaccharide residues with linear or branched structures~~.~~,

(ii) triterpene glycosides, containing an aglycone of alpha or beta-amyryl, lupane, hopane, dommarane, linostane or holostane series, and oligosaccharides comprising saccharide residues of branched or linear stricture~~,~~;

(iii) hydrophobic proteins capable of discriminately forming ~~a~~ complex ~~compound~~ compounds with cholesterol,

(iv) protein toxins~~,~~ capable of discriminately forming complex compounds with cholesterol,

(v) polyens antibiotics~~,~~ capable of discriminately forming complex compounds with cholesterol, and

(vi) enzymes having cholesterol as substrate and having a high affinity to cholesterol; and~~high affinity enzymes, whose substrate is cholesterol, and which have a high affinity to it,~~ ~~and~~ formation of said ~~colored~~ color complex is brought about by treatment of said ~~binding agent~~ reagent that selectively binds to cholesterol on the skin surface first with a visualizing agent and then with an indicating agent.

18. The process of ~~A process according to~~ claim ~~17~~ 16, wherein formation of said color complex is brought about by treatment of said cholesterol binding ~~agent~~ reagent on the skin surface successively with a bridging agent, a visualizing agent and an indicating agent.

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19. The process of claim 16 ~~A process according to claim 17 or claim 18~~, wherein said cholesterol binding ~~agent~~ reagent is digitonin.

20. The process of claim 17 ~~A process according to any one of claims 17 to 19~~, wherein said visualizing agent is peroxidase enzyme and said ~~indicator~~ indicating agent contains hydrogen peroxide~~,~~ and N,N-diethel-p-phenylidene sulfate, together with appropriate stabilizers.

21. A kit for determination of skin cholesterol levels ~~of~~ in a human patient, said kit comprising:

a source of detecting ~~agent~~ reagent, capable of binding to skin cholesterol of ~~the~~ said patient to form a bound combination therewith on the skin;

a source of visualizing agent~~,~~ capable of binding with ~~the~~ said detecting ~~agent-binding agent bound combination~~ reagent when said reagent is bound to skin cholesterol, to form an optically altered complex;

a source of developing agent and means for applying ~~the~~ said developing agent to ~~the~~ said optically altered complex, to develop color therein; and

means for confining and for presenting said optically altered complex to a portable ~~reflects~~ reflectance spectrophotometer to determine therefrom a defined color characteristic of said complex, said color characteristic being selected from the group consisting of hue angle, chroma ~~or~~ and saturation.

22. The kit of ~~A kit according to~~ claim 21, wherein said means of confining and presenting the optically altered complex to ~~the~~ said

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spectrophotometer comprises a container in the form of a skin-adherent strip having at least one well passing therethrough for containment of the reagents in said well in contact against the skin of the patient.

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